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Substitute for form 1449A/B/PTO		Application Number	09/281,430
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	March 30, 1999
(Use as many sheets as necessary)		First Named Inventor	INDU PARIKH
Sheet	1	Group Art Unit	1615
		Examiner Name	Todd Ware Carlos Azevedo
		Attorney Docket Number	402076-SKYEPHARMA

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Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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Examiner Signature	<i>Charles Azevedo</i>	Date Considered	<i>5/9/03</i>
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- A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/281,430
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Attorney Docket Number	402076 SKYEPHARMA

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		Application or Patent Number	Kind Code			
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Application Number 09/281,430

Filing Date March 30, 1999

First Named Inventor INDU PARIKH

Group Art Unit 1615

Examiner Name Todd Ware

Attorney Docket Number 402076 SKYEPHARMA

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Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARM

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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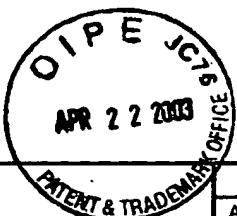
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
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09/281,430

March 30, 1999

INDU PARIKH

1615

Examiner Name

Todd Ware, Carlos, A2pura

Attorney Docket Number

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
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Application Number	09/281,430
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First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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	A240	6294191		Meers et al.	9/25/2001	
	A241	6294192		Patel et al.	9/25/2001	
	A242	6297985		Kang	10/2/2001	
	A243	6309623		Weers et al.	10/30/2001	
	A244	6312715		Cantor et al.	11/6/2001	
	A245	6326406		De Tommaso	12/4/2001	
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	A247	6331289		Klaveness et al.	12/18/2001	
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	A250	6350480		Urnezis et al.	2/26/2002	
	A251	6387409		Khan et al.	5/14/2002	
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	A253	6391832		Lyons et al.	5/21/2002	
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	A255	6410583		Labelle et al.	6/25/2002	
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	A257	RE32393		Wretlind et al.	4/7/1987	
	A258	RE35338		Haynes	9/24/1996	
	A259	2001/0007663		VON CORSWANT	7/12/2001	
	A260	2001/0046474		Weers et al.	11/29/2001	

Examiner Signature

Date Considered

5/9/05

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Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	9	of	13	Attorney Docket Number	402076 SKYEPHARMA
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### FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No <sup>+</sup>
	A 261		DE 2 513 797		Imperial Chemical Industries (see reference 4,056,635)	10/9/1975		X*
	A 262		DE 2 938 807		Green Cross Corp.	11/13/1980		X*
	A 263		DE 3 421 468		Dr. Rentschler Arzne. (see reference 4,880,634)	12/19/1985		X*
	A 264		DE 4 440 337		Rainer H. Müller (see reference 5,858,410)	5/15/1996		X*
	A 265		EP 0 036 277		Regents/ Univ. California	3/6/1981		
	A 262		EP 0 052 322		Gersonde, Klaus	5/26/1982		X*
	A 267		EP 0 153 926		Duncan H. Haynes	6/14/1984		
	A 268		EP 0 272 091		Vestar, Inc.	6/22/1988		
	A 269		EP 0 330 532		Fournier Industrie (see reference 4,895,726)	1/30/1989		X*
	A 270		EP 0 355 095		Liposome Comp., Inc.	8/4/1988		
	A 271		EP 0 391 369		Yissum Research Devel., Co.	4/4/1990		
	A 272		EP 0 418 153		Medgenix Group, S.A. (see reference 5,100,591)	3/20/1991		X*
	A 273		EP 0 456 670		B. Braun Melsungen AG	11/18/1993		X*
	A 274		EP 0 456 764		B. Braun Melsungen AG	9/1/1993		X*
	A 275		EP 0 499 299		Sterling Winthrop Inc.	8/19/1992		
	A 276		EP 0 570 829		Dr. Hans Dietl (see reference 5,527,537)	5/12/1993		X*
	A 277		EP 0 580 690		Sandoz Ltd.	2/2/1994		
	A 278		EP 0 589 843		Sandoz AG	9/21/1993		
	A 279		EP 0 601 618		Sterling Winthrop Inc.	10/30/1993		
	A 280		EP 0 605 497		Rainer Müller (see reference WO 93/05769)	3/20/1996		X*
	A 281		EP 0 724 877		Laboratoires Fournier S.C.A. (see reference 5,880,148)	8/7/1996		X*
	A 282		EP 0 757 911		CL Pharma (see reference 5,827,536)	2/12/1997		X*
	A 283		EP 0 770 381		L'OREAL (see reference 5,827,520)	5/2/1997		X*
	A 284		EP 0 602 700		Sterling Winthrop Inc.	12/1/1993		

Examiner Signature		Date Considered	5/9/05
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 10 of 13

		Complete if Known	
Application Number	09/281,430		
Filing Date	March 30, 1999		RECEIVED APR 23 2003 TECH CENTER 1600/200
First Named Inventor	INDU PARIKH		
Group Art Unit	1615		
Examiner Name	Todd Ware		
Attorney Docket Number	402076 SKYEPHARMA		

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No <sup>a+</sup>
CHP	A285		FR 2 617 047		Sanofiet Lab. Fournier	12-30-1988		X*
	A286		GB 1 527 638		Laboratories Fournier	3/20/1996		
	A287		GB 2 046 094		Technicon Instruments Corp.	4-8-1980		
	A288		GB 2 298 789		Zeneca Ltd.	3/17/1995		
	A289		HU 211 580B		FGIS (see reference 5,168,847)	6/20/1995		X*
	A290		JP 1502590		A. Nattermann & Cie (see reference WO 88/04924)	11/12/1980		X*
	A291		JP 5221852A		LT T Kenkyusho	8/31/1993		X*
	A292		JP 55141407		A. Nattermann & Cie (see reference 4,309,421)	11/5/1980		X*
	A293		JP 56167616		Green Cross Corp. (see reference 4,340,594)	5/15/1980		X*
	A294		JP 60208910		A. Nattermann & Cie	11/5/1980		X*
	A295		JP 63233915		Green Cross Corp. (see reference 5,320,906)	10/21/1985		X*
	A296		JP 63502117		Liposome Technology, Inc. (see reference WO 87/04592)	9/3/1986		X*
	A297		WO 00/10531		RTP Pharma Inc.	3/2/2000		
	A298		WO 00/24376		Abbott Laboratories	5/4/2000		
	A299		WO 00/40219		Dexcel Ltd.	7/13/2000		
	A300		WO 00/41682		LG Chemical Ltd.	7/20/2000		
	A301		WO 00/54588		John C. Krusz	9/21/2000		
	A302		WO 00/59471		Baxter International, Inc.	10/12/2000		
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	A306		WO 02/21517		Zeon Corp.	3/14/2002		
	A307		WO 85/00011		University of Miami	1/3/1985		
	A308		WO 87/04592		Liposome Technology, Inc.	8/13/1987		
	A309		WO 88/04924		Liposome Tech., Inc.	7/14/1988		
	A310		WO 91/16068		Duncan H. Haynes	10/31/1991		
	A311		WO 9104011		Riker Laboratories, Inc.	4/4/1991		

Examiner Signature	<i>John C. Krusz</i>	Date Considered	5/9/03
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Sheet 11 of 13

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Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware

Attorney Docket Number 402076 SKYEPHARMA

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### FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No <sup>+</sup>
Ch	A312		WO 92/18104		Vestar, Inc.	10/29/1992		
	A313		WO 92/18105		Sandoz Ltd.	10/29/1992		
	A314		WO 93/05768		Medac Gesellschaft	4/1/1993		
	A315		WO 93/19736		Kabi Pharmacia	10/14/1993		
	A316		WO 94/14415		Hemagen/PFC	7/7/1994		
	A317		WO 94/20072		Pharmacia AB	9/15/1994		
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	A320		WO 96/19064		Xcelenet, Inc.	6/20/1996		
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	A326		WO 98/41239		Nycomed	9/24/1998		
	A327		WO 98/53805		Saucy Limited	12-3-1998		
	A328		WO 99/29300		RTP Pharma	6/17/1999		
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Examiner Signature		Date Considered	5/9/03
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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of

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Complete if Known

Application Number	09/281,430
Filing Date	March 30, 1998
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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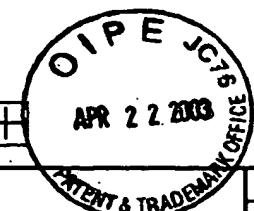
OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation Yes      No <sup>+</sup>
CR	A 333	[LSP4]La Fuma Polymery 1998 43 nr 2, 104-108, "The role of water-soluble polymers at the solid/liquid etc."	
	A 334	"Derived Diameters and Distribution Statistics," from an unknown web-site, 6 pages	
	A 335	"Getting Started", Man 0106, Issue 1.0, (Jan. 1996), <i>Malvern Instruments Ltd.</i> , England, pp. 7.1-7.7	
	A 336	BANGHAM et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids", <i>J. Mol. Biol.</i> (1965) 13, pp. 238-252	
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	A 339	BITTMAN, ROBERT, "Sterol-Polyene Antibiotic Complexation: Probe of Membrane Structure," <i>Lipids</i> , Vol. 13, No. 10, pp. 686-691 (1978).	
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	A 342	CHERNEY, L.S., "Tetracaine Hydroiodide: A Long Lasting Local Anesthetic Agent for the Relief of Postoperative Pain", <i>Anesth. Analg.</i> (1963) Vol. 42, No. 4, pp. 477-481	
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	A 349	HAYNES et al., "Metal-Ligand Interactions in Organic Chemistry and Biochemistry", <i>B. Pullman and N. Goldblum (eds.)</i> , part 2, (1977), pp. 189-212	
CR	A 350	HAYNES et al., "Ultra-Long Duration Local Anesthesia Produced by Injection of Leцитin-coated Methoxyflurane Microdroplets", <i>Anesthesiology</i> (1985) Vol. 63, No. 5, pp. 490-499	

Examiner Signature	<i>Indu Parikh</i>	Date Considered	5/9/03
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 13 of 13

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09/281,430

March 30, 1999

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1615

Todd Ware

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### OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
CH	A351	HERBERT A. LEIBERMAN and LEON LACHMAN, Eds., <i>Pharmaceutical Dosage Forms</i> , Tablets, Vol. 1, (1980), p. 13		
	A352	HUANG et al., "Interaction of the N-terminus of Sterol Carrier Protein 2 with Membranes: Role of Membrane Curvature", <i>Biochem. J.</i> , (1999) Vol. 8, pp. 593-603		
	A353	KIRKPATRICK et al., "Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man," <i>Anesthesiology</i> (1987) 67(3A): A254		
	A354	LEHNINGER BIOCHEMISTRY, "The Molecular Basis of Cell Structure and Function", (1970) Chapter 10		
	A355	LOURENCO et al., <i>Int. J. of Pharm.</i> 138 (1996), 1-12, "Steric stabilization of nanoparticles: size and surface properties".		
	A356	LUCKHAM <i>Pestic. Sci.</i> , 1989, 25, 25-34, "The Physical Stability of Suspension Concentrates with Particular etc."		
	A357	MISHRA et al., "Scientifically Speaking: Novel Injectable Formulations of Water-Insoluble Drugs", <i>Controlled Release Newsletter</i> , Vol. 17, Issue 2, (June 2000), pp. 21-30		
	A358	MIYAJIMA, KOICHIRO, "Role of Saccharides for the Freeze-Thawing and Freeze-Drying of Liposome", <i>Advanced Drug Delivery Review</i> , Vol. 24, (1997), pp. 151-159		
	A359	MULLER et al., "Nanosuspensions for the I.V. Administration of Poorly Soluble Drugs- Stability During Sterilization and Long-Term Storage", Dept. of Pharmaceutics, Biopharmaceutics and Biotechnology, The Free University of Berlin, Kelchstraße 31, D-12169 Berlin, Germany		
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	A361	NAPPER, "Polymeric Stabilizations of Colloidal Dispersions", (1983).		
	A362	PACE et al., "Novel Injectable Formulations of Insoluble Drugs", <i>Pharmaceutical Technology</i> , Vol. 23, No. 3, (March 1999), pp. 116-134		
	A363	ROMPP'S CHEMIE LEXIKON, 2 Aufl., Bd. 1, (1950), Stichwort, "Emulsion"		X
	A364	ROSS et al., "Aqueous Solutions of Surface-Active Solutes", <i>Colloidal Systems and Interfaces</i> , © 1988, pp. 148-151		
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	A366	SIEKMANN et al. <i>Pharm. Pharmacol Lett</i> (1994) 3:225-228 "Melt-homogenized Solid Lipid Nanoparticles Stabilized by the Non-ionic Surfactant Tyloxapol".		
	A367	Website <a href="http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm">http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm</a>		
	A368	WU et al., "Pharmacokinetics of Methoxyflurane After Its Intra-Dermal Injection as Lecithin-Coated Microdroplets", <i>Journal of Controlled Release</i> , (1989), Vol. 9, pp. 1-12		
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Examiner Signature

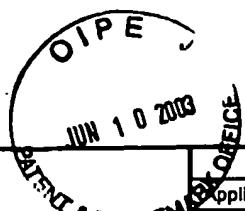
Date Considered

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	5	Attorney Docket Number	402076/SkyePharma
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Comple if Known

Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	PARIKH
Group Art Unit	1615
Examiner Name	T-Ware <i>Carlo S. Arpene</i>

U.S. PATENT DOCUMENTS					
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication
		Application or Patent Number	Kind Code		
<i>DA</i>	1	4,970,076		Horrobin	11/13/90
	2	5,342,625		Hauer et al.	8/30/94
	3	5,364,632		Benita et al.	11/15/94
	4	5,437,055		Wheatley, III	7/25/95
	5	5,603,951		Woo	2/18/97
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	7	5,652,212		Cavanak et al.	7/29/97
	8	5,696,153		Ainsworth et al.	12/9/97
	9	5,929,030		Hamied et al.	7/27/99
	10	6,004,573		Rathi et al.	12/21/99
	11	6,284,268		Mishra et al.	9/4/01

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Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No <sup>++</sup>
<i>DA</i>	12 ✓	EP	314 060		Warner-Lambert Co.	5/3/89		
	13 ✓	EP	539 319		Novartis AG	4/28/93		
	14 ✓	EP	589 843		Sandoz AG	3/30/94		
	15 ✓	EP	636 618		Marigen S.A.	2/1/95		X+
	16 ✓	EP	670 715		Gattefosse S.A.	9/13/95		X+
	17 ✓	EP	760 237		CIPLA Ltd.	3/5/97		
	18 ✓	UK	2 217 173		B A Whittle	10/25/89		
	19 ✓	WO	94/08603		Smith-Kline Beecham Corp.	4/28/94		
	20 ✓	WO	94/08605		Smith-Kline Beecham Corp.	4/28/94		
	21 ✓	WO	94/23733		DR. Rentschler Arzenemittel GMBH & Co.	10/27/94		X+
	22 ✓	WO	94/25068		Sherman	11/10/94		
	23 ✓	WO	95/11039		Hexal Pharma GMBH	4/27/95		X+
	24 ✓	WO	95/33490		Enzon, Inc.	12/14/95		
	25 ✓	WO	96/13273		Sandoz Ltd.	5/9/96		
	26 ✓	WO	96/35415		Sime et al.	11/14/96		
	27 ✓	WO	97/00080		Hexal AG	1/3/97		X+
	28 ✓	WO	97/02042		GS Development AB	1/23/97		
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	30 ✓	WO	97/19692		Sandoz-Patent-GMBH	6/5/97		
	31 ✓	WO	97/22358		Sherman	6/26/97		
	32 ✓	WO	97/25977		Novartis AG	7/24/97		
	33 ✓	WO	97/26003		Galena A S	7/24/97		
	34 ✓	WO	97/36610		Chong Kun Dang Corp.	10/9/97		

Examiner Signature	<i>DA</i>	Date Considered	<i>5/9/05</i>
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	2	of	5	Attorney Docket Number	402076/SkyePharma
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### Complete if Known

Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	PARIKH
Group Art Unit	1615
Examiner Name	T. Ware Cervicos A...
Attorney Docket Number	402076/SkyePharma

### OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
CJ	3 5	Arduino, M.J. et al., "Microbial Growth and Endotoxin Production in the Intravenous Anesthetic Propofol", Infection Control and Hospital Epidemiology, Vol. 12, No. 9, September 1991, pp. 535-539.	
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Examiner Signature		Date Considered	5/4/03
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	3	of	5	Attorney Docket Number	402076/SkyePharma
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### Complete if Known

Application Number 09/281,430  
Filing Date March 30, 1999  
First Named Inventor PARIKH  
Group Art Unit 1615  
Examiner Name T. Ware Carlos Apure

OTHER - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation		
			Yes	No <sup>++</sup>	
	52	Ghouri et al., "Effect of Flumazenil on Recovery after Midazolam and Propofol Sedation", Anesthesiology, (1994), Vol. 81, pp. 333-339.			
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Examiner Signature	<i>Carlo Apure</i>	Date Considered	<i>5/9/03</i>
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STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	PARIKH
Group Art Unit	1615
Examiner Name	T. Ware (Signature)

Attorney Docket Number 402076/SkyePharma

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation Yes	Translation No <sup>+</sup>
CJX	6 8	Tessler et al., "Growth curves of <i>Staphylococcus aureus</i> , <i>Candida albicans</i> , and <i>Moraxella osloensis</i> in propofol and other media", <i>Can. J. Anaesth.</i> (1992), Vol. 39 No. 5, pp. 509-511.		
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Examiner Signature	<i>Julie J.</i>	Date Considered	<i>5/4/03</i>
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Sheet 5 of 5

**Complete if Known**

Application Number 09/281,430

**Filing Date** March 30, 1999

First Named Inventor

First Named Inventor: PARKER

**Group Art Unit**

Examiner Name: 4. Vale CAV

Examiner Signature: *John D. Morris* Date Considered: *5/9/05*

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